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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,959	01/02/2002	David L. Hallahan	CL1792 US NA	4565

23906 7590 10/19/2004

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,959

Applicant(s)

HALLAHAN ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-31 and 34-40 is/are rejected.
- 7) ☒ Claim(s) 32 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on February 11, 2004), Applicants filed a response received on August 6, 2004 (no amendment to the claims). Thus, Claims 29-40 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/307,673 filed on July 25, 2001.

Information Disclosure Statement

3. The information disclosure statement filed on August 8, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Withdrawn - Objections to the Specification

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.
5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment to the abstract.

Maintained - Claim Objections

6. Previous objection to Claims 32-33 for depending from rejected claims is maintained because the rejections against the independent claims are herein maintained below.

Maintained - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 35 and 39-40 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that because the specification describes what promoters are by virtue of what they do that written description for the homologous promoter for SEQ ID NO:8 is described. This is not the case as previously clearly set forth in the rejection. While the genus of heterologous regulatory sequences is adequately described because the mere name of the genus indicates a specific structure and function, that is not the case for the endogenous or homologous promoter that would be adjacent to the polynucleotide encoding SEQ ID NO:8, which is clearly intended to be encompassed in the claimed scope as evidenced by Applicant's arguments citing both heterologous and non-heterologous regulatory sequences.

As previously noted,

"To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. The specification does not disclose a representative species of a homologous regulatory, with or without identifying characteristics. Therefore, Claims 35 and 39-40, as written, fails to satisfy the written description requirement. The Examiner suggests the insertion of the term "heterologous" into Claim 35 to obviate the instant rejection."

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8. Previous rejection of Claims 29-31 and 34-40 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that an alignment of SEQ ID NO:8, described as an acetyl-CoA acetyltransferase from the rubber tree, and a thiolase (gi:135759) from *Zoogloea ramigera* (a bacteria) indicates to one of skill in the art which 15% of residues can be mutated to maintained the acetyl-CoA acetyltransferase activity of the SEQ ID NO:8 sequence. The Examiner disagrees. The happenstance of residues being similar between two sequences does not define the sequences that govern the acetyltransferase activity of the protein. While information teaching experimentally identified active site residues (such as the Cys-X-Gly-X-Gly) is useful in making all the polynucleotides within the claimed scope, these few residues do not identify the breadth of as much as 85% identity and this motif is extremely common to enzymes across a broad array of substrates and catalytic activities. For these reasons, a single alignment does not teach the skilled artisan how to make the scope of the claimed invention, and the instant rejection is maintained.

Closest Prior Art

9. As previously noted, in EP 1033405 (see IDS) an *Arabidopsis thaliana* DNA fragment is taught that is 83% identical to a polynucleotide encoding SEQ ID NO:8. This does not meet the broadest limitations in the claims of 85% identical.

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Conclusion

10. Claims 29-31 and 34-40 are rejected; Claims 32-33 are objected to. Thus, Claims 29-40 are not allowed for the reasons identified in the numbered sections of this Office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

October 14, 2004